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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,231

Applicant(s)

ELLSON ET AL.

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-58 and 81-84 is/are pending in the application.
- 4a) Of the above claim(s) 11-18,50-53,55,57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,19-49,54,56 and 81-84 is/are rejected.
- 7) ☒ Claim(s) 82-83 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/29/00 & 7/31/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2004 has been entered.

Status of Claims

2. Applicant's response filed 10/27/2004 is acknowledged and entered.
3. Claims 1, 6-7, 9, 24, 54, and 56 amended by the amendment filed on 1/29/2004.
4. Claims 1, 3, 54, 56 amended and Claims 81-84 were added by the amendment filed on 7/28/2003.
5. Claims 2, and 59-80 were canceled by the amendment filed on 3/3/2003.
6. Claims 1, 3-58, and 81-84 are pending.

Election/Restrictions

7. Claims 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a ***nonelected invention***, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 9/18/2002.

8. Applicant has elected the following species for the elected invention (Claims 1-49, 54-58, and 81-84) in the reply filed on 9/18/2002:

a. Species (1) (Claims 6-10), temperature.

9. Claims 11-18, 55, 57, 58 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/18/2002.

10. Claims 1, 3-10, 19-49, 54, 56, and 81-84 are treated on the merit in this Office Action.

Claim Objections

11. Claim 82 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 83.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 82 recites wherein the indicator structure is comprised of a single-stranded oligonucleotide having defined sequences prehybridized to a labeled target. The labeled target is

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interpreted as a complementary single-stranded oligonucleotide with a label and the term “prehybridized” is interpreted as already formed ‘duplex’, i.e. double-stranded oligonucleotide. Claim 83 recites wherein the indicator structure is comprised of a double-stranded oligonucleotide having one labeled strand. Thus Claim 82 is a substantial duplicate of claim 83.

Claim Rejections - 35 USC § 112

12. Claims 81, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 81 is vague and indefinite because it is unclear as to the ability of the indicator structure to exhibit a response wherein the indicator structure is nucleotidic. It is unclear what constitutes the metes and bounds as to the ‘type’ of “detectable response” that is exhibits by the indicator structure when expose to the condition and lasted for at least one minute after removing from the condition as claimed in claim 1, i.e. what response is being ‘exhibits’ by a nucleotide when expose to the condition and lasted for at least one minute after removing from the condition? Thus claim 81 is vague and indefinite.

b) Claim 84 is vague and indefinite because it is unclear as to the ability of the indicator structure to exhibit a response wherein the indicator structure is wax. It is unclear what constitutes the metes and bounds as to the ‘type’ of “detectable response” that is exhibits by the indicator structure when expose to the condition and lasted for at least one minute after removing from the condition as claimed in claim 1, i.e. what response is being ‘exhibits’ by a wax when

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expose to the condition and lasted for at least one minute after removing from the condition?

Thus claim 81 is vague and indefinite.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455).

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. With regard to claim 54 the molecular moieties are nucleotidic molecular probes.

Cargill et al. disclose labeled libraries of random oligomers (device) (see e.g. Abstract; col. 1, lines 66 to col. 2, line 4; col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (see e.g. col. 7, lines 4-19; col. 7, line 53 to col. 8, line 15; col. 8, line 44-57; col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The synthesis support has a plurality of oligomer library members attached (see e.g. col. 11, lines

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51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The oligomers include polynucleotides (see. e.g. col. 8, lines 18-40; col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (see e.g. col. 12, lines 14-45; col. 14, lines 37-52). Therefore, the device of Cargill et al. anticipates the presently claimed device.

15. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093).

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides.

Bioarray discloses labeled libraries of beads (device) (see e.g. Abstract; pg. 7, line 16-30). The libraries of beads comprise beads (substrate), color codes (integrated indicator), and compounds (molecular moieties) (see e.g. pg. 17, lines 1-11; fig. 3). The bead comprises different areas wherein the color codes and compounds are attached (probe region and indicator region). The color codes would contain informations of events that occur with the compounds such as target binding and environmental monitoring (see e.g. pg. 17, line 14-27; pg. 20, lines 7-27). Therefore, the device of Bioarray anticipates the presently claimed device.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1, 3-10, 19-37, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617).

The instant claim 1 recites a device that comprises a substrate, a plurality of different molecular probes, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. The different molecular probes are attached to the probe region and interact with a corresponding target.

Cargill et al. disclose labeled libraries of random oligomers (device) (see e.g. Abstract; col. 1, lines 66 to col. 2, line 4; col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (see e.g. col. 7, lines 4-19; col. 7, line 53 to col. 8, line 15; col. 8, line 44-57; col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7).

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The synthesis support has a plurality of oligomer library members attached (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The oligomers include polynucleotides (see e.g. col. 8, lines 18-40; col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (see e.g. col. 12, lines 14-45; col. 14, lines 37-52).

The device of Cargill et al. differs from the presently claimed invention by failing to include a plurality of different molecular probes on the surface of the substrate.

Wang et al. disclosed a device in which the microarray would contain 10 or more different probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of different molecular probes on the surface of the substrate as taught by Wang et al. for the device of Cargill et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the device of Cargill et al. for the advantage of detecting multiple analytes since both Cargill et al. and Wang et al. disclose beads that are encoded with a binary code (Cargill: col. 10, lines 17-26; Wang: col. 7, lines 10-20). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Cargill et al. and Wang et al. because Wang et al. suggest that the number of probes on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of

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the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component.

19. Claims 1,⁶ and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. (*Proc. Natl. Acad. Sci.*, **1992**, 89(12):5381-5383) and Wang et al. (US Patent 5,922,617).

Brenner et al. disclose a combinatorial library of encoded compound (refers to the presently claimed device) and the method of two alternating parallel combinatorial syntheses wherein the genetic tag is chemically link to the chemical structure being synthesized (see e.g. Abstract; pg. 5381, right col., lines 30-54; pg. 5382, right col., line 34 to picture at top of pg. 5183). The combinatorial library of encoded compound comprises a genetic tag (refers to the presently claimed indicator structure), a solid support (refers to the presently claimed substrate), and peptide sequences (refers to the presently claimed probe) (see e.g. pg. 5382, right col., line 34 to picture at top of pg. 5183). The genetic tag is single-stranded oligonucleotide (refers to instant claims 81-82), which are detected by PCR after the combinatorial library of encoded compound is exposed to a binding assay (see e.g. pg. 5381, right col., lines 54-56; pg. 5383, left col., line 47 to pg. 5383, right col., line 34). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. pg. 5382, right col., lines 41-44; picture at top of pg. 5183).

The combinatorial library of encoded compound of Brenner et al. differs from the presently claimed invention by failing to include a plurality of different molecular probes on the surface of the substrate.

Wang et al. disclosed a device in which the microarray would contain 10 or more different probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of different molecular probes on the surface of the substrate as taught by Wang et al. in the combinatorial library of encoded compound of Brenner et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the combinatorial library of encoded compound of Brenner et al. for the advantage of detecting multiple analytes since both Brenner et al. and Wang et al. disclose beads that are encoded with a binary code (Brenner: pg. 5382, right col., lines 41-44; picture at top of pg. 5183; Wang: col. 7, lines 10-20). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Brenner et al. and Wang et al. because Wang et al. suggest that the number of probes on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (Wang: col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component.

Response to Arguments

20. Applicant's arguments, see pg 15, filed 10/27/2004, with respect to the rejection under 35 U.S.C. 112, first paragraph (new matter rejection), have been fully considered and are persuasive. The rejection under 35 U.S.C. 112, first paragraph (new matter rejection) of claims 1, 3-10, 19-49, 54, 56 and 81-84 has been withdrawn.

21. Applicant's arguments, see pg. 16, filed 10/27/2004, with respect to the rejection under 35 U.S.C. 112, first paragraph (new matter rejection), have been fully considered and are persuasive. The rejection under 35 U.S.C. 112, first paragraph (new matter rejection), of claims 1, 3-10, 19-49, 54, 56 and 81-84 has been withdrawn.

22. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455) for claims 54, and 56 was considered but they are not persuasive for the following reasons.

Applicant contends that the device of Cargill et al. does not anticipate the presently claimed device because 1) the indicator structure, i.e. identifier tag, of Cargill et al. does not change during the course of the exposure to the condition and 2) the information of the condition, i.e. temperature data, is added to the indicator structure. Thus the device of Cargill et al. does not anticipate the presently claimed device.

23. Applicant's arguments are not convincing since the device of Cargill et al. does anticipate the presently claimed device. 1) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant

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relies (i.e., the indicator structure change during the course of the exposure to the condition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). 2) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the information of the condition, i.e. temperature data, is added to the indicator structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus the device of Cargill et al. does anticipate the presently claimed device, and the rejection is maintained.

24. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093) for claims 56 was considered but they are not persuasive for the following reasons.

Applicant argues that the device of Bioarray Solutions LLC ("Bioarray") does not anticipate the presently claimed device because the information of the condition, i.e. temperature data, is added to the indicator structure. Thus the device of Bioarray Solutions LLC ("Bioarray") does not anticipate the presently claimed device.

Applicant's arguments are not convincing since the device of Bioarray Solutions LLC ("Bioarray") does anticipate the presently claimed device. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the

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features upon which applicant relies (i.e., the information of the condition, i.e. temperature data, is added to the indicator structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus the device of Bioarray Solutions LLC ("Bioarray") does anticipate the presently claimed device, and the rejection is maintained.

25. Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617) for claims 1, 3-10, 19-37, and 47-49 was considered but they are not persuasive for the following reasons.

Applicant alleges that the combination of Cargill et al. and Wang et al. is not obvious over the presently claimed invention because "*Cargill et al. is inapplicable to the above claims rejected under 35 U.S.C. § 103(a) for the same reasons that it was inapplicable to claims 54 and 56 under 35 USC § 102(b)*". Thus the combination of Cargill et al. and Wang et al. is not obvious over the presently claimed invention.

26. Applicant's arguments are not convincing since the combination of Cargill et al. and Wang et al. is obvious over the presently claimed invention. 1) Cargill et al. is applicable to the rejection under 35 USC 102(b) for claims 54, and 56 (see paragraph 22 above). Thus Cargill et al. is applicable for the rejection under 35 USC 103(a).

2) In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus the combination of Cargill et al. and Wang et al. is obvious over the presently claimed invention.

Allowable Subject Matter

27. The following is a statement of reasons for the indication of allowable subject matter:

The device having the combination of a substrate with a probe region and an indicator region, the probe region having a plurality of different probes, the indicator region having indicator structure comprising a double-stranded oligonucleotide having one labeled strand is not taught or fairly suggested by the cited prior arts of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
January 18, 2005


PADMASHRI PONNALURI
PRIMARY EXAMINER